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ACTAVIS TOTOWA LLC

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

DEPHLIA DAVIS, RHEA DAVIS AND JESSE GAYNOR, Plaintiffs, v. ACTAVIS GROUP, HF; ACTAVIS TOTOWA LLC; MYLAN, INC.; MYLAN PHARMACEUTICALS, INC.; and UDL LABORATORIES, INC., Defendants.	CASE NO. CV 08-3173 BZ HON. BERNARD ZIMMERMAN DEPARTMENT G **ANSWER OF ACTAVIS TOTOWA LLC TO PLAINTIFFS' COMPLAINT** **JURY DEMAND ENDORSED HEREIN**

Defendant Actavis Totowa LLC (hereinafter referred to as "Defendant") submits this Answer to Plaintiffs' Complaint.

I. INTRODUCTION

1. Defendant denies the allegations in paragraph 1 of Plaintiffs' Complaint.

2. Defendant admits that Digitek® is indicated for the treatment of heart failure and abnormal heart rhythms. Defendant admits that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an Abbreviated New Drug Application ("ANDA"), Mylan Pharmaceuticals distributed Digitek® under a "Bertek" label and UDL

Laboratories distributed Digitek® under a "UDL" label. Defendant denies the remaining allegations in paragraph 2 of Plaintiffs' Complaint.

3. Defendant admits that Digitek® was marketed as a safe and effective medication. Defendant denies the remaining allegations in paragraph 3 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by decedent William Davis ("Decedent") were defective.

4. Defendant admits that on April 25, 2008, Actavis Totowa initiated a voluntary nationwide recall of all lots of Digitek®. Defendant denies for want of knowledge, lack of information, and because they are not true the remaining allegations in paragraph 4 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

II. JURISDICTION AND VENUE

5. Defendant lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations in paragraph 5 of Plaintiffs' Complaint.

6. Defendant lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations in paragraph 6 of Plaintiffs' Complaint.

III. PARTIES

7. Defendant lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations in paragraph 7 of Plaintiffs' Complaint, and therefore denies the same.

8. Defendant lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations in paragraph 8 of Plaintiffs' Complaint, and therefore denies the same.

9. Defendant lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations in paragraph 9 of Plaintiffs' Complaint, and therefore denies the same.

10. Defendant admits that Actavis Group is an Icelandic corporation with its principal place of business in Iceland. Defendant denies the remaining allegations in paragraph 10, specifically denying that Actavis Group had any involvement in the activities regarding Digitek® as alleged in paragraph 10 of Plaintiffs' Complaint.

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11. Defendant admits that Actavis Totowa, LLC is a Delaware limited liability company with its principal place of business in New Jersey. Defendant denies the remaining allegations in paragraph 11 of Plaintiffs' Complaint.

12. Defendant admits that Mylan Inc. is a Pennsylvania corporation with its principal place of business in Pennsylvania. Defendant denies the remaining allegations in paragraph 12 of Plaintiffs' Complaint.

13. Defendant admits that Mylan Pharmaceuticals, Inc. is a West Virginia corporation with its principal place of business in West Virginia. Defendant denies the remaining allegations in paragraph 13 of Plaintiffs' Complaint.

14. Defendant admits that UDL Laboratories, Inc. is an Illinois corporation with its principal place of business in Illinois. Defendant denies the remaining allegations in paragraph 14 of Plaintiffs' Complaint.

15. Defendant admits that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, Mylan Pharmaceuticals distributed Digitek® under a "Bertek" label and UDL Laboratories, Inc. distributed Digitek® under a "UDL" label. Defendant denies the remaining allegations in paragraph 15 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

16. Defendant denies the allegations in paragraph 16 of Plaintiffs' Complaint, specifically denying that any breach of duty occurred.

17. Defendant admits that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, Mylan Pharmaceuticals distributed Digitek® under a "Bertek" label and UDL Laboratories, Inc. distributed Digitek® under a "UDL" label. Defendant denies the remaining allegations in paragraph 17 of Plaintiffs' Complaint.

18. Defendant denies the allegations in paragraph 18 of Plaintiffs' Complaint.

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IV. FACTUAL BASIS FOR THE CLAIMS ASSERTED

19. Defendant admits that Digitek® is a cardiac glycoside indicated for the treatment of heart failure and abnormal heart rhythms. Defendant denies the remaining allegations in paragraph 19 of Plaintiffs' Complaint.

20. Defendant admits that Digitek® is indicated for the treatment of heart failure and abnormal heart rhythms. Defendant denies the remaining allegations in paragraph 20 of Plaintiffs' Complaint.

21. Defendant denies for want of knowledge, lack of information, and because they are not true the allegations in paragraph 21 of Plaintiffs' Complaint.

22. Defendant admits that digoxin overdose and digitalis toxicity can cause serious injury and even death. Defendant denies the remaining allegations in paragraph 22 of Plaintiffs' Complaint, specifically denying that Decedent exhibited such symptoms or conditions as a result of his alleged use of Digitek®.

23. Defendant admits that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA.

24. Defendant admits that at all times relevant to the captioned matter, Mylan Pharmaceuticals distributed Digitek® under a "Bertek" label and UDL Laboratories Inc. distributed Digitek® under a "UDL" label.

25. Defendant admits that the Food and Drug Administration ("FDA") approved the sale of 0.125 mg and 0.250 mg dosages of Digitek®, but denies the remaining allegations in paragraph 25 of Plaintiffs' Complaint.

26. Defendant admits that the FDA approved the sale of 0.125 mg and 0.250 mg dosages of Digitek®, but denies the remaining allegations in paragraph 26 of Plaintiffs' Complaint.

27. Defendant admits that on April 25, 2008, Actavis Totowa initiated a voluntary nationwide recall of all lots of Digitek®. Defendant denies the remaining allegations in paragraph 27 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective.

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28. Defendant denies the allegations in paragraph 28 of Plaintiffs' Complaint.

29. Defendant admits that the FDA has issued "Good Manufacturing Practice" guidelines. The guidelines speak for themselves and, on that basis, Defendant denies the remaining allegations in paragraph 29 of Plaintiffs' Complaint.

30. Defendant denies the allegations in paragraph 30 of Plaintiffs' Complaint.

31. Defendant admits that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, but denies the remaining allegations in paragraph 31 of Plaintiffs' Complaint.

32. Defendant admits that the FDA issued a letter to Actavis Totowa on August 15, 2006. The letter speaks for itself. Defendant denies the remaining allegations in paragraph 32 of Plaintiffs' Complaint.

33. Defendant admits that the FDA issued a letter to Actavis Totowa on August 15, 2006. The letter speaks for itself. Defendant denies the remaining allegations in paragraph 33 of Plaintiffs' Complaint.

34. Defendant admits that the FDA issued a letter to Actavis Totowa on August 15, 2006. The letter speaks for itself. Defendant denies the remaining allegations in paragraph 34 of Plaintiffs' Complaint.

35. Defendant admits that the FDA issued a letter to Actavis Totowa on February 1, 2007. The letter speaks for itself. Defendant denies the remaining allegations in paragraph 35 of Plaintiffs' Complaint.

36. Defendant admits that the FDA issued a letter to Actavis Totowa on February 1, 2007. The letter speaks for itself. Defendant denies the remaining allegations in paragraph 36 of Plaintiffs' Complaint.

37. Defendant admits that Actavis Totowa issued a press release concerning the voluntary nationwide recall of Digitek® on April 25, 2008. The press release speaks for itself. Defendant denies the remaining allegations in paragraph 37 of Plaintiffs' Complaint.

38. Defendant denies the allegations in paragraph 38 of Plaintiffs' Complaint.

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39. Defendant denies the allegations in paragraph 39 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

V. CAUSES OF ACTION

FIRST CAUSE OF ACTION

Breach of Express Warranty

40. In response to paragraph 40 of Plaintiff's Complaint, Defendant realleges and incorporates by reference its answers to paragraphs 1 – 39 of Plaintiff's Complaint, as if fully set forth herein.

41. Defendant denies the allegations in paragraph 41 of Plaintiffs' Complaint, specifically denying the existence of any warranties in favor of, or representations to, Decedent and/or Plaintiffs by Defendant regarding Digitek®.

42. Defendant denies the allegations in paragraph 42 of Plaintiffs' Complaint, specifically denying the existence of any warranties in favor of, or representations to, Decedent and/or Plaintiffs by Defendant regarding Digitek® and that Decedent exhibited such symptoms or conditions as a result of his alleged use of Digitek®.

43. Defendant denies the allegations in paragraph 43 of Plaintiffs' Complaint, specifically denying the existence of any warranties in favor of, or representations to, Decedent and/or Plaintiffs by Defendant regarding Digitek®, that any Digitek® tablets used by Decedent were defective, and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

44. Defendant denies the allegations in paragraph 44 of Plaintiffs' Complaint, specifically denying the existence of any warranties in favor of, or representations to, Decedent and/or Plaintiffs by Defendant regarding Digitek®, that any Digitek® tablets used by Decedent were defective, and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

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45. Defendant denies the allegations in paragraph 45 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

46. Defendant denies the allegations in paragraph 46 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

47. Defendant denies the allegations in paragraph 47 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

SECOND CAUSE OF ACTION

Breach of Implied Warranty

48. In response to paragraph 48 of Plaintiff's Complaint, Defendant realleges and incorporates by reference its answers to paragraphs 1 – 47 of Plaintiff's Complaint, as if fully set forth herein.

49. Defendant admits that at all times relevant to this lawsuit, Digitek® was safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies the remaining allegations in paragraph 49 of Plaintiffs' Complaint, specifically denying the existence of any warranties in favor of, or representations to, Decedent and/or Plaintiffs regarding Digitek®.

50. Defendant denies the allegations in paragraph 50 of Plaintiffs' Complaint.

51. Defendant denies the allegations contained in paragraph 51 of Plaintiffs' Complaint, specifically denying the existence of any warranties in favor of, or representations to, Decedent and/or Plaintiffs regarding Digitek®.

52. The allegations in paragraph 52 state legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in paragraph 52 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

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53. Defendant denies the allegations in paragraph 53 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

54. Defendant denies the allegations in paragraph 54 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

55. Defendant denies the allegations in paragraph 55 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

THIRD CAUSE OF ACTION

Strict Product Liability - Failure to Warn

56. In response to paragraph 56 of Plaintiff's Complaint, Defendant realleges and incorporates by reference its answers to paragraphs 1 – 55 of Plaintiff's Complaint, as if fully set forth herein.

57. Defendant admits that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, Mylan Pharmaceuticals distributed Digitek® under a "Bertek" label and UDL Laboratories distributed Digitek® under a "UDL" label. Defendant denies the remaining allegations in paragraph 57 of Plaintiffs' Complaint.

58. Defendant denies the allegations in paragraph 58 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

59. Defendant denies for want of knowledge, lack of information, and because they are not true the allegations in paragraph 59 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

60. Defendant denies for want of knowledge, lack of information, and because they are not true the allegations in paragraph 60 of Plaintiffs' Complaint.

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61. Defendant denies the allegations in paragraph 61 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

62. Defendant denies the allegations in paragraph 62 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

63. Defendant denies the allegations in paragraph 63 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

64. Defendant denies the allegations in paragraph 64 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

65. Defendant denies the allegations in paragraph 65 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

66. Defendant denies the allegations in paragraph 66 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

67. Defendant denies the allegations in paragraph 67 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

FOURTH CAUSE OF ACTION

Strict Product Liability – Manufacturing Defect

68. In response to paragraph 68 of Plaintiff's Complaint, Defendant realleges and incorporates by reference its answers to paragraphs 1 – 67 of Plaintiff's Complaint, as if fully set forth herein.

69. Defendant admits that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, Mylan Pharmaceuticals distributed

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Digitek® under a "Bertek" label and UDL Laboratories distributed Digitek® under a "UDL" label. Defendant denies the remaining allegations in paragraph 69 of Plaintiffs' Complaint.

70. Defendant admits that Digitek® tablets were expected to reach patients without a substantial change in their condition from the time they were sold. Defendant denies the remaining allegations in paragraph 70 of Plaintiffs' Complaint.

71. Defendant denies the allegations in paragraph 71 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective.

72. Defendant denies the allegations in paragraph 72 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective.

73. Defendant denies the allegations in paragraph 73 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

74. Defendant denies the allegations in paragraph 74 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

75. Defendant denies the allegations in paragraph 75 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

76. Defendant denies the allegations in paragraph 76 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

FIFTH CAUSE OF ACTION

Fraud and Deceit

77. In response to paragraph 77 of Plaintiff's Complaint, Defendant realleges and incorporates by reference its answers to paragraphs 1 – 76 of Plaintiff's Complaint, as if fully set forth herein.

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78. Defendant denies the allegations in paragraph 78 of Plaintiffs' Complaint, specifically denying the existence of any representations to Decedent and/or Plaintiffs by Defendant and that any Digitek® tablets used by Decedent were defective.

79. Defendant denies the allegations in paragraph 79 of Plaintiffs' Complaint, specifically denying the existence of any representations to Decedent and/or Plaintiffs by Defendant and that any Digitek® tablets used by Decedent were defective.

80. Defendant denies the allegations in paragraph 80 of Plaintiffs' Complaint, specifically denying the existence of any representations to Decedent and/or Plaintiffs by Defendant and that any Digitek® tablets used by Decedent were defective.

81. Defendant denies the allegations in paragraph 81 of Plaintiffs' Complaint, specifically denying the existence of any representations to Decedent and/or Plaintiffs by Defendant and that any Digitek® tablets used by Decedent were defective.

82. Defendant denies the allegations in paragraph 82 of Plaintiffs' Complaint, specifically denying the existence of any representations to Decedent and/or Plaintiffs by Defendant, that any Digitek® tablets used by Decedent were defective, and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

83. Defendant admits that at all times relevant to the captioned matter, Actavis Totowa manufactured Digitek® pursuant to an ANDA, Mylan Pharmaceuticals distributed Digitek® under a "Bertek" label and UDL Laboratories distributed Digitek® under a "UDL" label. Defendant denies the remaining allegations in paragraph 83 of Plaintiffs' Complaint, specifically denying the existence of any representations to Decedent and/or Plaintiffs by Defendant.

84. Defendant denies the allegations in paragraph 84 of Plaintiffs' Complaint, specifically denying the existence of any representations to Decedent and/or Plaintiffs by Defendant.

85. Defendant denies the allegations in paragraph 85 of Plaintiffs' Complaint.

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86. Defendant denies the allegations in paragraph 86 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

87. Defendant denies the allegations in paragraph 87 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

88. Defendant denies the allegations in paragraph 88 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

89. Defendant denies the allegations in paragraph 89 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

SIXTH CAUSE OF ACTION

Negligent Misrepresentation

90. In response to paragraph 90 of Plaintiff's Complaint, Defendant realleges and incorporates by reference its answers to paragraphs 1 – 89 of Plaintiff's Complaint, as if fully set forth herein.

91. Defendant admits that at all times relevant to this lawsuit, Digitek® was safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies the remaining allegations in paragraph 91 of Plaintiffs' Complaint, specifically denying the existence of any representations to Decedent and/or Plaintiffs regarding Digitek®.

92. Defendant denies the allegations in paragraph 92 of Plaintiffs' Complaint, specifically denying the existence of any representations to Decedent and/or Plaintiffs by Defendant and that any Digitek® tablets used by Decedent were defective.

93. Defendant denies the allegations in paragraph 93 of Plaintiffs' Complaint, specifically denying the existence of any representations to Decedent and/or Plaintiffs by Defendant and that any Digitek® tablets used by Decedent were defective.

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94. Defendant denies the allegations in paragraph 94 of Plaintiffs' Complaint, specifically denying the existence of any representations to Decedent and/or Plaintiffs by Defendant and that any Digitek® tablets used by Decedent were defective.

95. Defendant denies the allegations in paragraph 95 of Plaintiffs' Complaint, specifically denying the existence of any representations to Decedent and/or Plaintiffs by Defendant, that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

96. Defendant denies the allegations in paragraph 96 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

97. Defendant denies the allegations in paragraph 97 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

98. Defendant denies the allegations in paragraph 98 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

99. Defendant denies the allegations in paragraph 99 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

SEVENTH CAUSE OF ACTION

Negligence and Negligence Per Se

100. In response to paragraph 100 of Plaintiff's Complaint, Defendant realleges and incorporates by reference its answers to paragraphs 1 – 99 of Plaintiff's Complaint, as if fully set forth herein.

101. Defendant admits that Actavis Totowa, Mylan Pharmaceuticals, and UDL Laboratories were subject only to those duties imposed by applicable law and denies that any such duty was breached. Defendant denies the remaining allegations in paragraph 101 of Plaintiffs' Complaint.

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102. Defendant denies the allegations in paragraph 102 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective.

103. Defendant denies the allegations in paragraph 103 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

104. Defendant denies the allegations in paragraph 104 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective.

105. Defendant denies the allegations in paragraph 105 of Plaintiffs' Complaint, specifically denying that any Digitek® tablets used by Decedent were defective and that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

106. Defendant denies the allegations in paragraph 106 of Plaintiffs' Complaint.

107. The allegations in paragraph 107 state legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations in paragraph 107 of Plaintiffs' Complaint.

108. Defendant denies the allegations in paragraph 108 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

109. Defendant denies the allegations in paragraph 109 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

110. Defendant denies the allegations in paragraph 110 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

111. Defendant denies the allegations in paragraph 111 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

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EIGHTH CAUSE OF ACTION

Negligent Infliction of Emotional Distress On Behalf of Dephlia Davis Only

112. In response to paragraph 112 of Plaintiff's Complaint, Defendant realleges and incorporates by reference its answers to paragraphs 1 – 111 of Plaintiff's Complaint, as if fully set forth herein.

113. Defendant lacks sufficient knowledge or information so as to form a belief as to the truth of the allegations in paragraph 113 of Plaintiffs' Complaint, and therefore denies the same.

114. Defendant denies the allegations in paragraph 114 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

115. Defendant denies the allegations in paragraph 115 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

116. Defendant denies the allegations in paragraph 116 of Plaintiffs' Complaint, specifically denying that Digitek® was the proximate cause of the injuries and damages alleged in Plaintiffs' Complaint.

PRAYER FOR RELIEF

Defendant denies that Plaintiffs are entitled to any recovery of damages contained in Plaintiffs' unnumbered Prayer for Relief.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

Plaintiffs' Complaint fails to state facts sufficient to constitute a cause of action against this Defendant.

SECOND AFFIRMATIVE DEFENSE

This Court lacks personal jurisdiction over this Defendant.

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THIRD AFFIRMATIVE DEFENSE

Plaintiffs are barred from any recovery against this Defendant by the doctrines of waiver and estoppel.

FOURTH AFFIRMATIVE DEFENSE

The Complaint is barred by reason of the doctrine of laches and by the fundamental unfairness and prejudice of the excessive and lengthy delay from the date of the alleged use of the subject pharmaceutical products to the filing of the Complaint.

FIFTH AFFIRMATIVE DEFENSE

Defendant states on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitation contained in California Code of Civil Procedure §§ 335.1 and 338 and former section 340(3), and such other statutes of limitation as may apply.

SIXTH AFFIRMATIVE DEFENSE

Any and all injuries suffered by Plaintiffs, the fact of which is expressly denied by this Defendant, were the direct and proximate result of sensitivities, medical conditions, reactions and/or idiosyncrasies peculiar to Decedent that were unknown, unknowable or not reasonably foreseeable to this Defendant, and not, as alleged, as a direct and proximate result of wrongful conduct on the part of this Defendant, the fact of which is expressly denied by this Defendant.

SEVENTH AFFIRMATIVE DEFENSE

No act or omission of this answering Defendant was a substantial factor in bringing about the alleged injuries of Decedent and/or Plaintiffs, nor was any such act or omission a contributing cause thereof, and any alleged acts or omissions of this Defendant were superseded by the acts or omissions of others, including Decedent and/or Plaintiffs, which were the

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independent, intervening and proximate cause of any injury, damage, or loss sustained by Plaintiffs.

EIGHTH AFFIRMATIVE DEFENSE

Defendant states on information and belief that any injuries, losses or damages suffered by Decedent and/or Plaintiffs were proximately caused, in whole or in part, by the failure of Decedent to exercise ordinary care and to follow the advice, information, warnings and/or instructions provided with the products and therefore, Plaintiffs' recovery, if any, must be diminished by the proportion of the negligence of Decedent which proximately caused or contributed to the alleged injuries, losses or damages.

NINTH AFFIRMATIVE DEFENSE

Defendant states on information and belief that any injuries, losses or damages suffered by the Decedent and/or Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than this Defendant. Therefore, Plaintiffs' recovery against this Defendant, if any, should be reduced pursuant to California Civil Code § 1431.2.

TENTH AFFIRMATIVE DEFENSE

Defendant states on information and belief that Decedent and/or Plaintiffs failed to mitigate their injuries, losses or damages, if any, suffered as a result of the incident and facts set forth in the Complaint.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries and damages, if any, were the result of the misuse of the subject pharmaceutical products at issue. Defendant further alleges that if Plaintiffs suffered injuries attributable to the use of the subject pharmaceutical products at issue in this suit, which allegations are expressly denied, the injuries, if any, were solely caused and attributable to the

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unreasonable, unforeseeable and improper use of said pharmaceutical products by Decedent and/or third parties.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiffs have failed to join all indispensable parties; as a result of such failure to join, complete relief cannot be accorded to those already parties to the action and will result in prejudice to this Defendant in any possible future litigation.

THIRTEENTH AFFIRMATIVE DEFENSE

The manufacture, distribution and sale of the pharmaceutical products referred to in Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiffs' causes of action are preempted.

FOURTEENTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs assert claims based on this Defendant's alleged adherence or lack of adherence to and compliance with applicable federal laws, regulations, and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiffs are barred from recovering against Defendant because Plaintiffs' claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq., and regulations promulgated thereunder, with the regulations promulgated by the Food and Drug Administration to implement the FDCA, with the purposes and objectives of the FDCA and the Food and Drug Administration's implementing regulations, and with the specific determinations by the Food and Drug Administration specifying the language that should be used in the labeling accompanying the subject pharmaceutical products.

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SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part under the applicable state law because the subject pharmaceutical products at issue were subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical products at issue under applicable federal laws, regulations, and rules.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

NINETEENTH AFFIRMATIVE DEFENSE

The warning, labeling, advertising and sale of the subject pharmaceutical products at issue complied at all times with the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 300 et seq. and the Federal Trade Commission Act, 15 U.S.C. § 41 et seq. Consequently, Plaintiffs' Complaint is preempted by these acts and compliance with these acts constitutes a complete or partial defense to the allegations of Plaintiffs' Complaint against Defendant, including any claim for punitive damages. Alternatively, Defendant is entitled to a presumption that the subject pharmaceutical products at issue are not defective or unreasonably dangerous and that their labeling was adequate.

TWENTIETH AFFIRMATIVE DEFENSE

If any pharmaceutical products distributed by this Defendant were involved in the incident alleged in the Complaint herein, which this Defendant denies, then and in that event,

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said pharmaceutical products were not defective at the time that they left the control of this Defendant.

TWENTY-FIRST AFFIRMATIVE DEFENSE

California's judicially-created definitions of manufacturing defect and design defect, and standards for determining whether there has been an actionable failure to warn, are unconstitutional in that, among other things, they are void for vagueness and an undue burden on interstate commerce, as well as an impermissible effort to regulate in an area that previously has been preempted by the federal government.

TWENTY-SECOND AFFIRMATIVE DEFENSE

The subject pharmaceutical products alleged in Plaintiffs' Complaint conformed to the then current state of the art. Further, the then current state of medical, scientific and industrial knowledge, art and practice was such that this Defendant did not know, and could not reasonably have known, that the subject pharmaceutical products might pose a risk of harm in normal and foreseeable use.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Defendant alleges that the pharmaceutical product at issue was fit and proper for its intended purpose and that the utility of the subject pharmaceutical product at issue outweighs any possible risk inherent in the use of the subject pharmaceutical product.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Defendant is informed and believes and thereon allege that, at or about the times, dates and places mentioned in the Complaint, if any risk was attendant upon Plaintiffs, which Defendant denies, Plaintiffs knew full well of such risk, were warned of such risk and voluntarily, and without compulsion or coercion, encountered and assumed such risk.

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TWENTY-FIFTH AFFIRMATIVE DEFENSE

The subject pharmaceutical product at issue has at all relevant times been available only upon the prescription of a licensed physician, and Decedent's prescribing physicians stood in the position of the learned intermediaries between Defendant and Plaintiffs. To the extent that Plaintiffs assert claims based on an alleged failure by Defendant to warn directly of alleged dangers associated with the use of the subject pharmaceutical product at issue, such claims are barred because Defendant had discharged its duty to warn in the warnings given to the prescribing physicians, under the learned intermediary doctrine.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims against Defendant are barred under § 6(c) of the Restatement of Torts (Third): Products Liability.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' strict liability claims are barred by the unavoidably dangerous product defense stated in Comment k to § 402A of the Restatement (Second) of Torts.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Defendant provided adequate "direction or warnings" as to the use of the subject pharmaceutical product at issue within the meaning of Comment j to § 402A of the Restatement (Second) of Torts.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

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THIRTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Defendant alleges that in the event that reliance was placed upon Defendant's nonconformance to an express representation, this action is barred since there was no reliance upon representations, if any, of this Defendant.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims of fraud and concealment are barred by reason of Plaintiffs' failure to allege the circumstances constituting the alleged fraud and concealment with particularity.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Defendant is informed and believes and thereon alleges that Plaintiffs failed to provide Defendant with timely notice of any alleged nonconformance with any express representation.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, the Full Faith and Credit Clause of the United States Constitution, and applicable provisions of the Constitution of the State of California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive

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damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages; if any; (5) permits jury consideration of net worth or other financial information relating to this Defendant; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs seek punitive damages for an alleged act or omission of this Defendant, no act or omission was oppressive, fraudulent, or malicious, under California Civil Code § 3294, and therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because all acts or omissions by this Defendant (or their agents or representatives) were privileged or justified and any claim based thereon is barred.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Plaintiffs lack standing to bring such claims.

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THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or in part because Defendant has been improperly joined in this action.

THIRTY-NINTH AFFIRMATIVE DEFENSE

Decedent and/or Plaintiffs were contributorily or comparatively negligent, which contributory or comparative negligence constitutes a proximate cause of harm to them.

FORTIETH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because Decedent would have taken the subject pharmaceutical products even if the subject pharmaceutical products' labeling contained the information that Plaintiffs contend should have been provided.

FORTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of accord and satisfaction.

FORTY-THIRD AFFIRMATIVE DEFENSE

Defendant is entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiffs with any other defendant or other person or entity.

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FORTY-FOURTH AFFIRMATIVE DEFENSE

To the extent that Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

FORTY-FIFTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs are seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

FORTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred in whole or part because they have been filed in an improper venue.

FORTY-SEVENTH AFFIRMATIVE DEFENSE

Defendant made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Decedent and/or Plaintiffs herein. If any such warranties were made, whether express or implied, which Defendant specifically denies, then Plaintiffs failed to give timely notice of any breach thereof.

FORTY-EIGHTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs seek restitution on behalf of individuals who used the subject pharmaceutical products and suffered no damage or loss as a result thereof, restitution is unavailable as nothing has been taken from those individuals, who allegedly could have an equitable basis for restitution.

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FORTY-NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claims for restitution for products previously used are barred in whole or in part because Decedent received benefits from the subject pharmaceutical products and nothing was wrongfully taken from Decedent and/or Plaintiffs.

FIFTIETH AFFIRMATIVE DEFENSE

Defendant intends to rely upon such other affirmative defenses as may become available or apparent during the course of investigation, discovery, or trial, and reserves the right to amend the Answer to assert such other defenses to which it may be entitled.

PRAYER

WHEREFORE, Defendant prays for judgment as follows:

1. That Plaintiffs take nothing from Defendant by reason of the Complaint;

2. That the Complaint be dismissed;

3. That Defendant be awarded its costs for this lawsuit;

4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' alleged injuries, losses or damages is attributable to each person;

5. That any judgment for damages against Defendant in favor of Plaintiffs be no greater than an amount which equals its proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' injuries and damages; and

6. That Defendant have such other and further relief as the Court deems appropriate.

DATED: August 8, 2008 TUCKER ELLIS & WEST LLP

By: /S/ Peter E. Schnaitman
Peter E. Schnaitman
Attorneys for Defendant
ACTAVIS TOTOWA LLC

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JURY DEMAND

Defendant Actavis Totowa LLC, hereby demands a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

DATED: August 8, 2008

TUCKER ELLIS & WEST LLP

By: /S/ Peter E. Schnaitman
Peter E. Schnaitman
Attorneys for Defendant
ACTAVIS TOTOWA LLC

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CERTIFICATE OF SERVICE

I, Maria Valdez, declare as follows:

I am employed with the law firm of Tucker Ellis & West LLP, whose address is 515 South Flower Street, Suite 4200, Los Angeles, California 90071-2223. I am over the age of eighteen years, and am not a party to the within action.

On August 8, 2008, I served the following: **ANSWER OF ACTAVIS TOTOWA LLC TO PLAINTIFF'S COMPLAINT** on the interested parties in this action by:

X **ELECTRONICALLY VIA ECF** the above-entitled document to be served electronically through the United States District Court, Northern Division ECF website on August 8, 2008 addressed to all parties appearing on the Court's ECF service list. The file transmission was reported as complete and a copy of the "Filing Receipt" page will be maintained with the original document in our office.

X **(FEDERAL):** I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made.

Executed at Los Angeles, California on August 8, 2008.

/S/ Maria Valdez
Maria Valdez

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